NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CENTENE CORP., *et al.*, Plaintiffs, v. MERCK & CO., INC., *et al.*, Defendants.	Case No. 2:23-cv-23033 (BRM) (LDW) **OPINION**

MARTINOTTI, DISTRICT JUDGE

Before this Court is Defendants Merck & Co., Merck Sharp & Dohme Corp., Schering-Plough Corporation, Schering Corporation (collectively, "Merck"), and Glenmark Pharmaceuticals Limited's ("Glenmark") (together with Merck, "Defendants") Partial Motion to Dismiss (ECF No. 43) Plaintiffs Centene Corporation ("Centene"), Wellcare Health Plans, Inc. ("Wellcare"), New York Quality Healthcare Corp., d/b/a Fidelis Care ("Fidelis"), and Health Net, LLC's ("Health Net") (collectively, "Plaintiffs") Amended Complaint ("Amended Complaint") (ECF No. 35) pursuant to Federal Rule of Civil Procedure 12(b)(6).[1] Plaintiffs oppose the motion (ECF No. 44), and Defendants filed a reply (ECF No. 45).

[1] This case is one of two that were originally filed in the District of New Jersey, *see Centene Corp. v. Merck & Co., Inc., et al.*, Case No. 2:23-cv-23033 (D.N.J. Sept. 22, 2021), and then consolidated in a Multi-District Litigation ("MDL") in the Eastern District of Virginia by the JPML pursuant to 29 U.S.C. § 1407, *see Centene Corp. v. Merck & Co, et al.*, Case No. 2:21-cv-17363 (E.D. Va. Oct. 18, 2021); *Humana Inc. v. Merck & Co, et al.*, Case No. 2:21-cv-01007 (E.D. Va. Oct. 18, 2021). At the time Centene was joined to the MDL, there were at least seven other actions ongoing with common questions of fact. On December 12, 2023, the JPML remanded both cases back to this Court. (ECF No. 10.) The two cases are represented by the

Having reviewed the parties' submissions filed in connection with the Motion and having declined to hold oral argument pursuant to Federal Rule of Civil Procedure 78(b), for the reasons set forth below and for good cause having been shown, Defendants' Partial Motion to Dismiss (ECF No. 43) is **GRANTED** in part and **DENIED** in part.

I. BACKGROUND

For the purpose of this Motion to Dismiss, the Court accepts the factual allegations in the Amended Complaint as true and draws all inferences in the light most favorable to Plaintiffs. *See Philips v. Cnty. Of Alleghany*, 515 F.3d 224, 228 (3d Cir. 2008). The Court also considers any "document integral to or explicitly relied upon in the complaint." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

Plaintiffs' Amended Complaint concerns "Merck's overarching monopolistic scheme, Merck and Glenmark's anticompetitive settlement agreement, and Merck, Par, and Glenmark's unlawful business arrangement [which] violated numerous State antitrust and consumer protection laws." (ECF No. 35 ¶ 8.)

A. The Parties

Centene is a Delaware corporation with its principal place of business in St. Louis, Missouri. (*Id.* ¶ 9.) Centene and its subsidiaries provide healthcare related services, including "insuring risk for prescription drug costs for more than 15.2 million insureds in all 50 States, the District of Columbia, and Puerto Rico." (*Id.* ¶ 9.) Several of Centene's subsidiaries are co-plaintiffs in this litigation, including: (1) WellCare, a Delaware corporation with a principal place of business in Tampa, Florida, which was acquired by Centene on January 23, 2020 (*Id.* ¶ 10); (2) Fidelis, a New York corporation in Rego Park, New York, which was acquired by Centene on

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same attorneys and raise roughly the same claims against Defendants, who submitted identical briefs in support of their Motions to Dismiss against the two Plaintiffs.

July 1, 2018 (*Id.* ¶ 11); and (3) Health Net, a Delaware limited liability company with a principal place of business in Los Angeles, California, which was acquired by Centene on March 24, 2016 (*Id.* ¶ 12).

Merck & Co., Inc. is a corporation organized under the laws of New Jersey. (*Id.* ¶ 13.) Merck Sharp & Dohme Corp. is a subsidiary of Merck & Co., Inc., organized under the laws of New Jersey and the assignee of patents relevant to this matter. (*Id.* ¶ 14.) MSP Singapore Co. LLC is a subsidiary of Merck with a principal place of business in Kenilworth, New Jersey, and formerly the exclusive licensee of the relevant patents. (*Id.* ¶ 20.) Schering-Plough Corp. ("Schering-Plough") was also a corporation organized under the laws of New Jersey, as was Schering Corp. ("Schering"), a wholly owned subsidiary of Schering-Plough and the original assignee of the relevant patents. (*Id.* ¶¶ 15–16.) Merck & Co. acquired Schering-Plough in 2009 and thereafter merged and changed its name to Merck & Co., Inc., and the company formerly known as Merck & Co., Inc. became Merck Sharp & Dohme Corp. (*Id.* ¶ 17.)

Glenmark Pharmaceuticals Limited is an Indian corporation with a principal place of business and registered office in Mumbai, India. (*Id.* ¶ 18.) Glenmark Pharmaceuticals Inc., USA ("Glenmark"), a wholly owned subsidiary of Glenmark Pharmaceuticals Limited incorporated in 2002, is a corporation with a principal place of business in New Jersey that has been referred to, done business as, or been known as both Glenmark Pharmaceuticals Inc., USA and Glenmark Generics Inc., USA. (*Id.* ¶ 21.)

Par Pharmaceutical, Inc. is a corporation under the laws of New York. (*Id.* ¶ 19.) Par Pharmaceutical, Inc. is a subsidiary of Endo International plc ("Endo"), an Irish corporation with a headquarters in Malvern, Pennsylvania. (*Id.*) Endo acquired Par Pharmaceutical Holdings, Inc. and its subsidiaries (including Par Pharmaceutical, Inc.) and merged it with its existing generics

subsidiary, Qualitest Pharmaceuticals. (*Id.*) The Amended Complaint refers to all of Par's predecessors and successors, collectively, as "Par." (*Id.*)

B. The Regulatory Structure for Approval of New Drugs

Before releasing a new pharmaceutical product into the market, companies must first file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA") providing information on any relevant patents and demonstrating the safety and efficacy of the proposed drug. (ECF No. 35 ¶ 25.) Once approved, the FDA creates a list of information regarding any patents identified as covering the proposed drug by the manufacturing company—specifically, patents: (1) claiming the approved drug or its approved uses; and (2) for which a patent infringement claim could be reasonably asserted under 21 U.S.C. §§ 355(b)(1) and (c)(2)—in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). (*Id.* ¶ 26.) The FDA relies on a company's representations about the validity and applicability of asserted patents. (*Id.* ¶ 27.) The drugs covered by NDAs are commonly referred to as "brand-name drugs" or "branded drugs," and pharmaceutical companies that receive NDA approval are entitled to a 180-day period of "regulatory exclusivity[]" as a first-filer, during which time the FDA cannot approve any other similar generic drug applications. (*Id.* ¶¶ 25, 28, 32.) However, the manufacturer of the brand drug is still entitled to market and sell its own authorized generic version during this exclusivity period, thereby capturing some of the sales that would otherwise go to a first filer of a generic version. (*Id.* ¶ 32.)

"Generic versions of brand-name drugs contain the same active ingredient as the branded drug and have been determined by the FDA to be just as safe and effective as the brand." (*Id.* ¶ 37.) When brand manufacturers release their own generics during the exclusivity period, the price of the generic drug drops, as do sales of the brand-name drug. (*Id.* ¶ 44.) In fact, according to the Federal Trade Commission, first-filers make considerably less money in sales when facing

competition from an authorized generic because the authorized generic takes a large portion of the overall sales and prices of both generic drugs drop. (*Id.*)

Under the Hatch-Waxman Act, when the exclusivity period of a branded drug nears expiration, a manufacturer of a generic version of that drug can submit an Abbreviated New Drug Application ("ANDA") demonstrating that the proposed generic is "essentially the same as the branded version[.]" (*Id.* ¶ 29.) For FDA approval, a manufacturing company: (1) certifies that its proposed generic does not infringe of any patents listed in the branded drug's Orange Book; and (2) includes one of the following four certifications:

> a. Paragraph I Certification: No patent for the branded drug has been filed with the FDA;
> b. Paragraph II Certification: The patent for the branded drug has expired;
> c. Paragraph III Certification: The patent for the branded drug will expire on a particular date, and the manufacturer does not seek to market its generic drug before that date; or
> d. Paragraph IV Certification: The patent for the branded drug is invalid or will not be infringed by a generic manufacturer's proposed product.

(*Id.* ¶ 30 (citing 21 U.S.C. § 355(b)(2)(A)(i)–(iv)) (emphasis added).) Filing a Paragraph IV Certification can delay FDA approval of the ANDA if the brand manufacturer initiates a lawsuit against the generic manufacturer for patent infringement within forty-five days of receiving notification of the certification. (*Id.* ¶ 31.) In such cases, the FDA will not approve the ANDA "until the earlier of: (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid, unenforceable, or not infringed by the generic manufacturer's proposed product." (*Id.*) Brand manufacturers have considerable incentives to prevent generic entry, such as by suing any competitors that file an ANDA with a Paragraph IV certification, because it automatically triggers a 30-month stay of the approval process. (*Id.* ¶ 35.)

C. Heart Disease and the Alleged Significance of Merck's Cholesterol-Reducing Drugs

"Heart disease is the leading cause of death in the United States, accounting for 1 out of every 4 deaths[,]" and one of the major risk factors for heart disease is high cholesterol (*Id.* ¶ 1.) According to the Amended Complaint, cholesterol—a critical component of the myelin sheath of animal cell membranes that insulates nerve cells and facilitates nerve impulses—is either made in the liver or absorbed through the intestines from food and comes in two forms: low-density lipoprotein ("LDL") and high-density lipoprotein ("HDL"). (*Id.* ¶¶ 50–52.) Researchers in the 1970s and 1980s began exploring how to reduce liver production of harmful LDL, resulting in the development of a family of drugs called statins. (*Id.* ¶ 53.) The most profitable drugs in pharmaceutical history for many years, statins have since been widely used to treat nearly 13 million patients with high LDL cholesterol. (*Id.* ¶ 55.) For example, Merck launched Zocor, a statin whose generic version is simvastatin, in 1998 and it became a huge success. (*Id.* ¶ 54.) For roughly 60% of those patients, however, even the use of statins cannot achieve their target LDL cholesterol reduction. (*Id.* ¶ 55.) Consequently, pharmaceutical companies have developed highly successful alternative drugs to reduce LDL production and avoid the significant side effects of regular statins (*Id.*)

Merck has developed and marketed several ground-breaking drugs aimed at reducing cholesterol; namely, "Zetia, the first drug in a new class of lipid-lowering medications, and Vytorin, a fixed-dose combination pill comprised of Zetia and simvastatin[,]" which have been among the best-selling cholesterol treatment drugs of the last fifteen years with more than $2 billion in sales in some years. (*Id.* ¶ 2.) Merck entered into a joint venture with Schering-Plough Pharmaceuticals to develop new cholesterol-lowering drugs that would address the deficiencies of statins. (*Id.* ¶ 56.) First, by the early 2000s, the joint venture had developed Zetia, which

worked by inhibiting cholesterol absorption through the intestine. (*Id.*) As part of the joint venture and prior to the merger of the two companies in 2009, they agreed to share equally in the development, promotion, costs, and profits of any jointly developed drugs, except the first $300 million earned on Zetia, of which Schering-Plough would receive a larger portion. (*Id.* ¶ 58.) On December 27, 2001, Merck and Schering-Plough filed an NDA for Zetia, which was approved by the FDA on October 22, 2002, and Zetia entered the market within days of the NDA's approval. (*Id.* ¶ 57.) Then, on July 23, 2004, Merck released its next cholesterol-lowering drug, Vytorin, which combined Zetia and a statin to help the many patients who saw significantly lower cholesterol levels with a combination drug. (*Id.* ¶ 62.) After the merger between Merck and Schering-Plough, Merck was the sole owner of Zetia, Vytorin, and other drugs that emerged from the joint venture. (*Id.* ¶ 58.)

Zetia was an instant success, bringing in U.S. sales of almost $1 billion in 2010 and $1.6 billion by 2016. (*Id.* ¶ 59.) Its appeal comes from the fact it can work alone or in combination with statins to address the unique health issues of each patient (*Id.* ¶ 60); in fact, according to Merck, roughly "half of Zetia prescriptions were for "statin-intolerant" patients and the other half were for patients who needed Zetia to complement their statin prescriptions" (*Id.* ¶ 61). Vytorin was likewise a massive success. (*Id.* ¶ 62.)

Plaintiffs allege that, to protect its monopoly over these drugs, Merck asserted both the U.S. Patent No. RE 37,721 (the "RE '721" patent) and the U.S. Patent No. 5,846,966 (the "'966" patent). (*Id.* ¶ 63.) The RE '721 patent, which Merck asserted covered Zetia, expired on April 25, 2017, including pediatric exclusivity of an additional six months. (*Id.*) The '966 patent allegedly covered the Vytorin combination of Zetia and a statin and expired on March 21, 2014, including pediatric exclusivity. (*Id.*)

D. Defendants' Allegedly Anticompetitive Conduct

Plaintiffs generally allege Defendants engaged in an overarching scheme to monopolize the distribution of Zetia and Vytorin in the U.S., including a purportedly anticompetitive settlement agreement ("Zetia Settlement Agreement") between Merck and Glenmark and alleged unlawful business arrangements between Merck, Par, and Glenmark, in violation of federal and state antitrust laws, and state consumer protection and unjust enrichment laws. (ECF No. 35 ¶ 8.)

1. Merck's Allegedly Inequitable Conduct During FDA Approval Process of the '115 and RE '721 Patents, and Glenmark's ANDA Application for a Generic Version of Zetia

The Amended Complaint alleges Schering prosecuted a family of patents, including the '115 patent, from the 1990s through the 2000s, during which time Schering, Merck, and MSP Singapore had a duty to disclose "all information known . . . to be material to patentability" to the U.S. Patent and Trademark Office ("USPTO"). (ECF No. 35 ¶ 65 (quoting 37 C.F.R. § 1.56).) However, Schering, Merck, and MSP allegedly did not disclose potentially relevant publications, such as one concerning laboratory experiments that resulted in the metabolization of compounds SCH48461 and SCH58235, also known as ezetimibe (generic Zetia), using well-known methods. (*Id.* ¶¶ 66–68.) Consequently, Defendants were able to obtain patent claims that, Plaintiffs contend, impermissibly covered naturally occurring and widely known compounds. (*Id.* ¶ 68.)

Later, Plaintiffs suggest Merck violated its duty to inform the FDA of any patents covering Zetia during the approval process by allegedly listing some patents that did not cover Zetia and improperly asserting other patents against pharmaceutical companies seeking generic approval for the drug. (*Id.* ¶¶ 69–73.) Moreover, when Merck listed the RE '721 in the Orange Book, Plaintiffs allege it "knew or should have known [] the patent was invalid" or otherwise unenforceable due to "its [] inequitable conduct[.]" (*Id.* ¶ 74.) With FDA approval for Zetia,

Merck obtained a five-year exclusivity grant and an additional grant of pediatric exclusivity for six months. (*Id.* ¶¶ 81–82.) On October 25, 2006, Glenmark filed an ANDA for a generic version of Zetia. (ECF No. 35 ¶ 83.) Glenmark's ANDA application included a Paragraph IV Certification asserting the patents listed in Zetia's Orange Book, but the FDA could not approve the ANDA until the following year because of Merck's exclusivity. (*Id.*)

2. Merck Used Same Zetia Patents to Allegedly Stop Generic Competition to Vytorin

In response to the looming expiration of Zocor's patent and regulatory exclusivity in 2006, Plaintiffs allege Merck decided to combine Zocor and Zetia into a single tablet, which allowed Merck to stretch Zetia's patent protection over Zocor. (ECF No. 35 ¶¶ 142–43.) In 2003, MSP Singapore filed an NDA for this new combination product, Vytorin, and received FDA approval on July 23, 2004, which gave Merck exclusivity until October 25, 2007. (*Id.* ¶ 143.) Plaintiffs allege Merck marketed Vytorin as a "unique dual-inhibition therapy," even though Vytorin prescriptions contained the same combination of doses as Zocor and Zetia, which were often prescribed in tandem. (*Id.* ¶ 144.) According to Plaintiffs, Vytorin became a highly successful drug and generated billions of dollars in sales. (*Id.* ¶ 145.) After March 21, 2014, Merck's exclusive right over Vytorin was based on the RE '461 patent alone. (*Id.* ¶ 146.)

3. Schering's Lawsuit Against Glenmark Alleging Infringement of the RE '721 Patent

On March 22, 2007, Schering and MSP, as the patent's assignee and exclusive licensee, respectively, sued Glenmark in the U.S. District Court for the District of New Jersey alleging infringement of the RE '721 patent. (ECF No. 35 ¶ 84.) Plaintiffs allege this lawsuit was meritless because Merck "effectively admitted" the '966 and '106 patents were invalid, unenforceable, and/or did not cover Zetia by failing to assert claims the patents would be

infringed by the Glenmark generic. (*Id.*) But merely by initiating the suit, Schering and MSP triggered an automatic 30-month stay, during which time the FDA was prevented from approving Glenmark's ANDA until expiration of the 30 months or entry of a final judgement that the RE '721 patent was invalid, unenforceable, and/or not infringed, which Plaintiffs allege was Merck's true aim. (*Id.*) In its responsive pleadings, Glenmark asserted various affirmative defenses and counterclaims, arguing—as Plaintiffs in this matter do—that Schering engaged in inequitable conduct and violated its duty of disclosure to the USPTO in its filing of the RE '721 patent. (*Id.* ¶¶ 85–92.) While the lawsuit was ongoing, the FDA approved Glenmark's ANDA, which gave it a 180-day exclusivity period as the first-filer for a Zetia generic. (*Id.* ¶ 94.) However, Plaintiffs allege that, due to the 30-month litigation stay, Glenmark was still precluded from releasing its generic. (*Id.*)

4. Schering and Glenmark Sign a Settlement Agreement, Which Includes an Alleged Reverse Payment Scheme

Plaintiffs allege Defendants unlawfully restrained trade and illegally grew their monopoly over the U.S. market for Zetia and Vytorin product, in part through the Zetia Settlement Agreement, which purportedly included a reverse payment scheme by which Merck paid Glenmark not to compete with its Zetia and Vytorin product. (*Id.* ¶¶ 186 n.18, 198 n.19, 210, 231, 233.) Plaintiffs contend that, a few months after the FDA granted tentative approval to Glenmark's ANDA for Zetia and while the parties were discussing a possible settlement, Glenmark's lead negotiator sent Glenmark executives an email summary with key points from a meeting with Schering's general counsel. (ECF No. 35 ¶ 96.) In that email, he noted "I . . . reminded [Schering's general counsel] of the fact that [the] court decision in favor of Glenmark will impact Vytorin product." (*Id.*)

On May 10, 2010, days before trial in Schering's action against Glenmark was set to begin, the parties settled, agreeing that Glenmark would not release its generic Zetia drug for five years until December 12, 2016. (*Id.* ¶ 97.) According to Plaintiffs, this settlement agreement ensured that the RE '721 patent would not be invalidated by the suit and protected "both Zetia and Vytorin from generic competition." (*Id.* ¶ 98.)

Plaintiffs allege that, under sections 5.2 and 5.4 of the settlement agreement, Glenmark would not launch its generic drug before December 12, 2006 (absent certain conditions), and under section 5.3, Merck would not launch an authorized generic version of its own "[d]uring any period of exclusivity to which Glenmark [wa]s entitled under 21 U.S.C. § 355(j)(5)(B)(iv) [180-day exclusivity], and through the expiration of [Merck's] rights under the RE '721 Patent and Ezetimibe Pediatric Exclusivity." (*Id.* ¶ 112.) In other words, Glenmark was free to launch its generic drug on December 12, 2006, Merck's exclusivity period for the RE '721 patent ended on April 25, 2017, and Glenmark's exclusivity expired on June 10, 2017. (*Id.*)

Plaintiffs also allege circumstantial evidence of the existence of this reverse payment scheme, including: (1) Merck had a history of releasing authorized generics amidst competition from generic manufacturers, and had admitted this practice was in its financial interest; (2) Zetia was a highly successful drug and an authorized generic would likely have been profitable; (3) Merck did not launch an authorized generic during Glenmark's 180-day period of exclusivity, even though it was not prohibited by law and had a record of doing so in the past; (4) Glenmark's press release announcing its generic drug described it as "the first and only generic version" of Zetia in the U.S.; and (5) before releasing its drug, Glenmark told its shareholders it expected to capture more than 58% of combined brand and generic sales, which it purportedly did within six months, whereas a generic manufacturer would typically achieve a significantly

smaller share of market sales. (*Id.* ¶ 114.) Plaintiffs allege competing generic versions of Zetia ordinarily would have been released when Merck's regulatory exclusivity period ended on December 6, 2011. (*Id.* ¶ 117.) By then, the FDA had approved Glenmark's ANDA and Merck had no remaining rights of exclusivity. (*Id.* ¶ 118.)

5. The Distribution Agreement Between Glenmark and Par

While Schering's lawsuit was still ongoing, Glenmark entered into an agreement with Par ("Distribution Agreement") by which Par would have the exclusive right to market, distribute, and sell Glenmark's generic version of Zetia in the United States in exchange for an upfront payment to Glenmark and a net profit-sharing arrangement. (ECF No. 35 ¶ 103.) Under the Distribution Agreement, Glenmark was required to "keep Par reasonably informed regarding material developments made with respect to any Litigation[,]" presumably including the Schering lawsuit, and was bound to confer with Par on "all material decisions with respect to the Litigation [which would] be made jointly[.]" (*Id.* ¶ 104.) The Distribution Agreement also included a provision to create a joint Steering Committee to advise, monitor, and otherwise oversee the marketing, distribution, and sale of the drug. (*Id.* ¶ 106.) Plaintiffs contend, pursuant to the terms of the Agreement, Par consented to the reverse payment agreement between Merck and Glenmark, *see supra* Section I.D.4. (*Id.* ¶ 105.)

6. Filings with Paragraph IV Certifications for Generic Zetia Products from Competing Manufacturers

Plaintiffs allege a second pharmaceutical company, Mylan Pharmaceuticals, Inc. ("Mylan") filed a Paragraph IV Certification for its own generic version of the branded drug around April 2010. (ECF No. 35 ¶ 132.) Merck filed a lawsuit against Mylan alleging infringement of the RE '721 and '966 patents (the latter of which was later withdrawn) raising many of the same arguments it made against Glenmark. (*Id.*) The FDA approved an ANDA

application for Mylan's generic on August 7, 2013, but because its case against Merck was still ongoing, it was precluded from entering the market. (*Id.*) On July 21, 2010, a third company, Teva Pharmaceuticals ("Teva") filed for FDA approval of a generic while Merck's case against Mylan was still pending. (*Id.* ¶ 133.) Merck sued Teva a few months later, and on July 7, 2011, the two parties entered into a settlement agreement in which Teva agreed not to launch its generic product before April 25, 2017. (*Id.*) Similarly, another company, Sandoz, notified Merck of its ANDA filing for a generic Zetia in August 2012. (*Id.* ¶ 134.) Merck sued Sandoz for infringement of the RE '461 patent on September 27, 2012, and a year later, on September 5, 2013, the parties settled and, like Teva, Sandoz agreed not to release its generic Zetia until April 25, 2017. (*Id.*)

7. Reissuance of the RE '721 Patent

Plaintiffs allege Schering applied for a reissuance of the RE '721 patent on June 9, 2010, and admitted its "belie[f] the original patent to be wholly or partly inoperative or invalid[.]" (*Id.* ¶ 99.) During the proceeding, Schering's attorneys allegedly proposed amendments to, and cancellations of, several claims based on inherent anticipation and invalidity. (*Id.* ¶ 100.) They also disclosed several publications Plaintiffs allege were critical and wrongfully withheld from the information provided to the patent examiner during the '115 and RE '721 patent approval processes. (*Id.* ¶ 101.) The RE '721 patent was reissued as the RE '461 patent on June 14, 2011. (*Id.*) Plaintiffs allege the reissuance was an attempt by Merck "to insulate itself from other ANDA filers for Zetia using the dispositive defenses asserted by Glenmark." (*Id.*)

8. Generic Versions of Zetia Enter the Market

Plaintiffs allege Glenmark released its generic version of Zetia on December 12, 2016, the first such generic to enter the market. (ECF No. 35 ¶ 135.) Glenmark's generic was the only one being sold in the United States, as Merck did not release its own authorized generic version,

until on or about June 12, 2017, when Glenmark's 180-day exclusivity period ended. (*Id.* ¶¶ 137–39.) On or about June 12, 2017, the FDA approved ANDAs for new generic versions of Zetia by seven competitor companies. (*Id.* ¶ 139.)

9. Plaintiffs' Causes of Action

Plaintiffs' Amended Complaint concerns "Merck's overarching monopolistic scheme, Merck and Glenmark's anticompetitive settlement agreement, and Merck, Par, and Glenmark's unlawful business arrangement [which] violated numerous State antitrust and consumer protection laws." (*Id.* ¶ 8.)

Specifically, Plaintiffs assert the following causes of action: (1) Monopolization in Violation of Various State Antitrust Laws against Merck (Count I) (*Id.* ¶¶ 184–195); (2) Conspiracy to Monopolize in Violation of Various State Antitrust Laws against all Defendants (Count II) (*Id.* ¶¶ 196–207); (3) Conspiracy to Restrain Trade in Violation of Various State Antitrust Laws against all Defendants (Count III) (*Id.* ¶¶ 208–19); (4) Unfair and Deceptive Trade Practices in Violation of Various State Unfair Competition and Consumer Protection Laws against all Defendants (Count IV) (*Id.* ¶¶ 220–28); (5) Monopolistic Scheme in Violation of Various State Antitrust Laws against Merck (Count V) (*Id.* ¶¶ 229–36); and (6) Unjust Enrichment Under State Law against all Defendants (Count VI) (*Id.* ¶¶ 237–48).

E. Procedural History

On September 22, 2021, both Centene and Humana Inc. ("Humana"), represented by the same counsel, filed suit in two separate actions against Defendants in the District of New Jersey. (*See* ECF No. 1.) *Humana Inc., et al. v. Merck & Co., Inc., et al.*, Case No. 2:23-cv-23023 (D.N.J. Sept. 22, 2021) (ECF No. 1). On October 19, 2021, both cases were transferred from this Court to the Eastern District of Virginia to be part of the MDL. (ECF No. 5). By the time

Centene and Humana filed their respective suits, at least seven other actions involving common questions of fact were transferred by the JPML pursuant to 29 U.S.C. § 1407. (*Id.*)

Two years later, on December 12, 2023, the JPML remanded the *Centene* and *Humana* cases to the District of New Jersey, the original transferor court, following the completion of pretrial proceedings. (ECF No. 10 at 1); *Centene Corp. v. Merck & Co.*, Case No. 2:21-cv-01008 (E.D. Va. Dec. 12, 2023). On February 13, 2024, in response to a letter submitted by Humana and Defendants pursuant to oral instructions at a status conference in the *Humana* case, Magistrate Judge Leda D. Wettre ordered that the *Centene* and *Humana* cases should not be consolidated and directed the parties to meet and confer and submit a proposed briefing schedule for motions to dismiss going forward. (ECF No. 34.)

On April 29, 2024, Merck filed this Partial Motion to Dismiss all Vytorin-related claims; Plaintiffs' primary theories of liability for monopolization, monopolistic scheme, conspiracy to monopolize; and all state law claims. (ECF No. 43.) Also on April 29, 2024, Plaintiffs opposed the Motion (ECF No. 44) and Defendants filed a reply (ECF No. 45).

II. LEGAL STANDARD

In deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court is "required to accept as true all factual allegations in the complaint and draw all inferences from the facts alleged in the light most favorable to [the non-moving party]." *Phillips*, 515 F.3d at 228 ("[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations."); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted). However, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." *Twombly*, 550 U.S. at 545 (alterations in original). A court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S.

265, 286 (1986). Instead, assuming factual allegations in the complaint are true, those "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 663 (citing *Twombly*, 550 U.S. at 556). This "plausibility standard" requires the complaint allege "more than a sheer possibility that a defendant has acted unlawfully," but it "is not akin to a 'probability requirement.'" *Id.* at 678 (citing *Twombly*, 550 U.S. at 556); *see also In re Generic Pharms. Pricing Antitrust Litig.*, MDL 2724, 16-MD-2724, Case No. 20-3539, 2023 WL 2244685, at *4 (E.D. Pa. Feb. 27, 2023) ("On a motion to dismiss, the Court 'consider[s] plausibility, not probability.'"). "[D]etailed factual allegations" are not required, but "more than an unadorned, the-defendant-unlawfully-harmed-me accusation" must be pled; it must include "factual enhancements" and not just conclusory statements or a recitation of the elements of a cause of action. *Id.* (citations omitted). In assessing plausibility, the Court may not consider any "[f]actual claims and assertions raised by a defendant." *Doe v. Princeton Univ.*, 30 F.4th 335, 345 (3d Cir. 2022).

"Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* (quoting Fed. R. Civ. P. 8(a)(2)). Indeed,

after *Iqbal*, it is clear that conclusory or "bare-bones" allegations will no longer survive a motion to dismiss: "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 678. To prevent dismissal, all civil complaints must now set out "sufficient factual matter" to show that the claim is facially plausible. *Iqbal*, 556 U.S. at 677. This "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678. The Supreme Court's ruling in *Iqbal* emphasizes that a plaintiff must show that the allegations of his or her complaints are plausible. *See id.* at 670. "However, [p]laintiffs are not required 'to plead facts that, if true, definitively rule out all possible innocent explanations.'" *In re Generic Pharms.*, 2023 WL 2244685 at *4. Furthermore, "it is improper at this stage of the proceedings to weigh alternatives and [decide] which is more plausible." *Id.* (quoting *In re Broiler Chicken Antitrust Litig.*, 290 F. Supp. 3d 772, 788 (N.D. Ill. 2017).

While, as a general rule, the Court may not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to Rule 12(b)(6), the Third Circuit has held that "a court may consider certain narrowly defined types of material without converting the motion to dismiss [to one for summary judgment under Rule 56]." *In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999). Specifically, courts may consider any "document *integral to or explicitly relied upon* in the complaint." *In re Burlington Coat Factory*, 114 F.3d at 1426 (emphasis added) (quoting *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1220 (1st Cir. 1996)). However, "[w]hen the truth of facts in an 'integral' document are contested by the well-pleaded facts of a complaint, the facts in the complaint must prevail." *Princeton Univ.*, 30 F.4th at 342.

III. DECISION

Plaintiffs' claims against Defendants are premised on allegations that Defendants sought and/or achieved an illegal monopoly through a series of actions that resulted in Plaintiffs, as well as the greater public, paying artificially high prices for cholesterol-lowering medications and

harming competition in the U.S. markets for generic versions of those drugs. (ECF No. 35 ¶¶ 1–8.) Defendants move to dismiss: (1) the *Per Se* Monopoly theory from Count III; (2) all claims seeking Vytorin-related damages; (3) all state law claims asserted in Counts I–VI; (4) the Monopolization theories of *Walker Process*[2] fraud, sham litigation, and Orange Book listing from Counts I and V; (5) the Monopolistic Scheme claim (Count V); and (6) the Conspiracy to Monopolize with Schering theory from Counts II.

A. *Per Se* Monopoly Theory – Count III

In Count III of the Amended Complaint, Plaintiffs allege the Zetia Settlement Agreement is an illegal reverse payment agreement designed to restrain trade. (ECF No. 35 ¶¶ 209–10.) As Defendants are direct competitors, Plaintiffs argue this agreement is a horizontal agreement and constitutes a *per se* violation of federal antitrust laws, given it aimed to "effectively fix the prices for Zetia and Vytorin at supracompetitive levels." (*Id.* ¶ 209.) Alternatively, Plaintiffs contend this agreement is an unreasonable restraint of trade under a rule of reason analysis because any pro-competitive justifications for the agreement are outweighed by its anticompetitive effects. (*Id.* ¶ 212.)

According to Defendants, Plaintiffs' theory that the Zetia Settlement Agreement between Merck and Glenmark was unlawful *per se* should be dismissed because Plaintiffs agreed "to be bound by an order the MDL court issued dismissing claims that are identical." (ECF No. 43 at 39.) Plaintiffs concede the MDL court's dismissal of the theory that the settlement agreement was *per se* unlawful is binding, although "Plaintiffs do not concede the correctness of [the] ruling[.]" (ECF No. 44 at 11 n.4.) Defendants reiterate this stipulation bars Plaintiffs' *per se* theory. (ECF No. 45 at 9.)

[2] This theory arises out of the Supreme Court's decision in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 389 U.S. 172, 174 (1965).

Given the parties' stipulation to be bound by the MDL Court's Order dismissing the *per se* theory of liability, Defendants' motion to dismiss the *per se* theory from Count III is **GRANTED**.

B. All Claims Seeking Vytorin-Related Damages – All Counts (I–VI)

Plaintiffs allege they suffered damages as a result of Defendants' monopolistic scheme by paying artificially high prices not only for generic and brand-name Zetia but also for Vytorin. (ECF No. 35 ¶¶ 195, 207, 219, 225, 235, 243.) Although Plaintiffs rely on conduct related to brand-name and generic Zetia, they seek recovery of damages for allegedly supracompetitive prices of Vytorin because Zetia constitutes one of its key ingredients. *See id.*; *supra* Section I.C. And because there are no "reasonably interchangeable substitutes for Zetia," Plaintiffs allege prices for Zetia products affect the price of Vytorin. (*Id.* ¶ 169.)

Defendants argue Plaintiffs' claims for Vytorin damages relating to alleged violations of federal and state antitrust laws fail because: (1) Plaintiffs fail to allege antitrust standing, given their theory of liability depends on many attenuated links in a causal chain (ECF No. 43 at 29–35); and (2) they fail to allege the settlement agreement between Merck and Glenmark regarding Zetia was intended to "target" Vytorin as well (*Id.* at 35–38). Plaintiffs respond that notice pleading does not require it to specify the extent to which its members would have switched to generic alternatives in the absence of the challenged conduct at this stage of the litigation. (ECF No. 44 at 17–18.) Instead, Plaintiffs point to allegations that they could have implemented various tried-and-true methods to encourage patients to replace brand-name Vytorin's single pill with a two-pill combination of generic Zetia and generic Zocor at a fraction of the cost. (*Id.* at 21–22.) Plaintiffs contend these allegations support a plausible inference that at least some of its members would have switched but for the purportedly anticompetitive actions of Defendants.

(*Id.*) This, according to Plaintiffs, suffices to establish antitrust standing for its Vytorin claims. (*Id.* at 20–21.)

1. Directness and Causal Connection Factors under *Associated Gen. Contractors* ("*AGC*")[3]

Defendants argue Plaintiffs' "two-pill" theory is too indirect to confer antitrust standing as it "hinges on independent choices by innumerable individuals that sever the causal chain." (ECF No. 43 at 32.) In response, Plaintiffs contend Defendants "erroneously collapse" the *AGC* factors of directness and causal connection into a proximate cause factor. (ECF No. 44 at 21.) As to directness, Plaintiffs contend Defendants do not cite any cases requiring that the allegedly anticompetitive conduct affirmatively target the product that is the locus of a request for damages. (*Id.* at 30.) Even if Plaintiffs were required to show Vytorin was specifically targeted, Plaintiffs argue they met their burden by alleging the email communications between Defendants during negotiations over the Zetia Settlement Agreement, establishing Defendants recognized Vytorin sales would be affected if generics of Zetia were able to go to market. (*Id.* at 31.) Additionally, Plaintiffs assert Defendants' case citations are factually irrelevant. (*Id.* at 31–32.)

Additionally, Plaintiffs contest Defendants' characterization of the causality required under *AGC*. (*Id.* at 28–29.) Plaintiffs argue that the possible existence of some intervening factors does not, on its own, preclude standing. (*Id.*) Plaintiffs also assert it is not required to eliminate all possible intervening, contributory factors at this stage but must only "show that a violation is a 'material cause' of the claimed injury." (*Id.* at 28 (quoting *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, MDL No. 2445, 13-MD-2445, Civ. A. No. 16-5073, 2017 WL 4910673, at *11 (E.D. Pa. Oct. 30, 2017).) Furthermore, damages

[3] *See Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519 (1983).

claims should not be dismissed at the pleadings stage, according to Plaintiffs, because Plaintiffs have sufficiently provided Defendants with enough notice of the basis of the claims with respect to liability as well as damages. (*Id.* at 18–19.)

Federal law permits a broad class of persons to bring private antitrust suits, namely, "any person" injured "by reason of anything" prohibited by law. 15 U.S.C. § 15(a). The Supreme Court has narrowed the standing statute and articulated bedrock principles to consider in making determinations of antitrust standing. *See AGC*, 459 U.S. at 545; *Hawaii v. Standard Oil Co. of Cal.*, 405 U.S. 251, 262 n.14 (1972) ("Congress did not intend the antitrust laws to provide a remedy in damages for all injuries that might conceivably be traced to an antitrust violation."); *see also Host Int'l, Inc., v. MarketPlace, PHL, LLC*, 32 F.4th 242, 249 (3d Cir. 2022) ("While the name echoes the familiar formulation of Article III, the judicially imposed requirement of antitrust standing is far more limiting."). The Third Circuit clarified five general factors relevant to the standing analysis, based on the Supreme Court's guidance in *AGC*:

> (1) a causal connection between an antitrust violation and harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages.

In re Lower Lake Erie Iron Ore Antitrust Litig. ("*Lake Erie*"), 998 F.2d 1144, 1165–66 (3d Cir. 1993). *Lake Erie* emphasized that "antitrust injury is more than a component to be factored in a standing analysis" and "must be present in every case," as it is a necessary, albeit insufficient, condition of standing. *Id.* at 1166; *see also Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178, 182 (3d Cir. 1997).

It has long been established that "the judicial remedy cannot encompass every conceivable harm that can be traced to alleged wrongdoing." *AGC*, 459 U.S. at 536. Put differently, there is a strong presumption limiting recovery in statutory causes of action to those alleged injuries proximately caused by a violation of that statute. *See Lexmark Int'l, Inc., v. Static Control Components, Inc.*, 572 U.S. 118, 132 (2014). Because the lack of statutory standing precludes recovery, courts must dismiss claims that fail to establish each and every element of standing. *See Animal Sci. Prods., Inc. v. China Minmetals Corp.*, 34 F. Supp. 3d 465, 485 (D.N.J. 2014) ("[S]tatutory standing is a threshold issue . . . . "); *accord NicSand, Inc., v. 3M Co.*, 507 F.3d 442, 449 (6th Cir. 2007) ("[W]e not only may—but we must—reject claims under Rule 12(b)(6) when antitrust standing is missing.").

Regarding the first *AGC* factor as outlined in *Lake Erie*, courts have found causal connections in cases alleging numerous intervening links in a causal chain. *See Lifewatch Servs. Inc. v. Highmark Inc.*, 902 F.3d 323, 342 (3d Cir. 2018) (finding a causal link in spite of intervening factors "such as [the health plan's] independent ability to decline coverage of telemetry monitors, a doctor's choice not to prescribe telemetry monitors, and a patient's desire for alternative treatments"); *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 401 (3d Cir. 2000) (concluding plaintiff had antitrust standing even with "various links of middlemen"); *but see Allegheny General Hosp. v. Philip Morris, Inc.*, 116 F. Supp. 2d 610, 615 (W.D. Pa. 1999) (finding plaintiffs' claims too remote and indirect because they were neither consumers of, nor competitors with, defendants' products); *Reading Industries, Inc. v. Kennecott Copper Corp.*, 631 F.2d 10, 14 (2d Cir. 1980) (affirming district court's finding that causal relationship between defendants' alleged antitrust violation and plaintiff's alleged harm "too tenuous and conjectural" given, among other reasons, it sought to connect conduct across distinct markets). A causal link

between an antitrust violation and harm to the plaintiff is "highly speculative" when the injury alleged is "extremely remote[.]" *Broadcom Corp v. Qualcomm Inc.*, 501 F.3d 297, 320 (3d Cir. 2007). The Supreme Court has evaluated the first and second factors of causation and injury together, effectively merging them into a single concept of "antitrust injury." *See Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 113 (1986); *Brunswick Corp v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977) ("Plaintiffs must prove antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful.").

The third and fourth factors of directness and the existence of more direct victims of the antitrust violation "are interrelated," and each helps to clarify the requisite analytical framework of the other. *Hanover 3201 Realty, LLC v, Village Supermarkets, Inc.*, 806 F.3d 162, 177 (3d Cir. 2015). "A plaintiff can suffer direct injury even if the defendant's anticompetitive conduct ultimately targets a third party." *Id.* Here, the parties agree *AGC* and its progeny govern how courts should assess antitrust standing but disagree on the requirements of causation and directness within that framework. (ECF No. 44 at 20; ECF No. 45 at 9.)

The Court finds Plaintiffs plead a sufficient causal chain. (ECF No. 43 at 32.) The Court agrees with Plaintiffs that the number and relationships between and among the links in the causal chain are quite common, even mundane, for the theory being alleged in such a complex industry. (ECF No. 44 at 23); *see also Novell, Inc. v. Microsoft Corp.*, 505 F.3d 302, 316–17 (4th Cir. 2007) (finding plaintiff sufficiently demonstrated causation, and ultimately showed antitrust injury, despite plaintiff and defendant not directly competing in the same market). Moreover, Plaintiffs' allegations on causation go beyond mere speculation, as Defendants' own internal communications indicate an awareness of the significant effects their conduct regarding Zetia

would inevitably have on Vytorin products. (ECF No. 35 ¶ 96 (quoting an email from Glenmark's lead negotiator during its ANDA approval process in which he "reminded [Schering's general counsel] of the fact that [the] court decision in favor of Glenmark will impact Vytorin product").)

Defendants' reliance on *Broadcom* on the causation issue is unpersuasive. (ECF No. 43 at 33.) In *Broadcom*, plaintiff Broadcom alleged that Qualcomm, a supplier of telecommunications technology, was illegally maintaining a monopoly across several markets for certain technologies, including chipsets. 501 F.3d at 319–20. Broadcom, a company yet to enter the relevant chipset market but which had purchased a chipset developer, argued that because the majority of cellphone manufacturers were subject to Qualcomm's monopoly power in these markets, Qualcomm marshalled its power over consumers in the markets to destroy competitors' chipset business. *See id.* The Circuit Court dismissed Broadcom's claims as lacking a causal connection because the Complaint did not sufficiently show an intention by Qualcomm to cause harm to Broadcom, and Broadcom's theory could not account for why Qualcomm's direct competitors in these markets did not themselves file lawsuits alleging similar illegal monopolization claims. *Id.* at 321. In stark contrast, Plaintiffs allege Defendants knew the agreement between Merck and Glenmark would directly impact the cost of Vytorin, and Plaintiffs are direct competitors of Defendants in the market for generic drugs.

Similarly, the Court finds sufficient allegations of direct harm caused by Defendants' activities. Courts generally agree plaintiffs asserting antitrust claims must be market participants because otherwise "their injuries are too secondary and indirect to be considered 'antitrust injuries.'" *Delco LLC v. Giant of Maryland, LLC*, Civ. No. 07-3522, 2007 WL 3307018, at *9 (D.N.J. Nov. 8, 2007) (quoting *Serfecz v. Jewel Food Stores*, 67 F.3d 591, 597 (7th Cir. 1995)).

The directness factor is therefore satisfied when the plaintiff is a market participant in *direct* competition with the defendant and plausibly alleges harm intended at the plaintiff. *See id.* Here, although most allegations focus on Zetia and not Vytorin, Plaintiffs cite Defendants' internal communications to allege knowledge Defendants actions would affect Vytorin. (ECF No. 35 ¶ 96.) Taking this as true, Plaintiffs sufficiently allege Vytorin-related harm was, if not in the first post-conduct ripple, close enough in the causal chain to be considered so near as to be practically first. *See AGC*, 459 U.S. at 534 (quoting *Blue Shield of Virginia v. McCready*, 457 U.S. 465, 476 (1982)). The Court can easily construct a causal chain to find the loss is "conceivably [] traced to the conduct of the defendants." *Schwab Short-Term Bond Market Fund v. Lloyds Banking Group PLC*, 22 F.4th 103, 116 (2nd Cir. 2021) (quoting *In re Aluminum Warehousing Antitrust Litig.*, 833 F.3d 151, 157 (2d Cir. 2016)). Plaintiffs' allegations reveal a closer causal connection than Defendants contend, and sufficiently allege a direct competitor relationship between the parties.

Defendants' reliance on *Reading* as support for its argument of indirect harm is unavailing. (ECF No. 43 at 31.) That case—in which the plaintiff alleged a conspiracy among defendants to keep prices of refined copper artificially low resulted in it paying higher prices in the market for copper scraps—involved a web of complex allegations that defendants' conduct in one market resulted in injury to the plaintiff in a distinct, albeit related, second market. *See Reading*, 631 F.2d at 13. While Defendants argue Plaintiffs concede their theory of harm connects the "actions of innumerable individual decision-makers[,]" *id.*, Plaintiffs' causal chain is critically different from the one in *Reading*. Where the court in *Reading* was asked to accept a causal chain that traversed two distinct markets and involved untold actors whose decision-making was independent and unknowable, *id.*, here, Plaintiffs posit a much shorter chain within a

single market, involving a limited set of actors whose decision-making processes are well known. (ECF No. 35 ¶ 152; ECF No. 44 at 21–24.) Indeed, Plaintiffs note such a causal chain is "present in every pharmaceutical pay-for-delay case." (ECF No. 44 at 23.)

2. Intended Target of Alleged Anticompetitive Conduct

Plaintiffs allege, in both the Amended Complaint and the Opposition to the Motion to Dismiss, that their injuries "were precisely the intended consequence of Defendants' anticompetitive conduct." (ECF No. 44 at 22; ECF No. 35 ¶ 113.) In their Motion to Dismiss, Defendants argue this position fails to support claims for Vytorin damages because the Zetia Settlement Agreement did not target Vytorin. (ECF No. 43 at 35.) Defendants note that courts regularly find claims to be impermissibly indirect where a plaintiff seeks recovery for injuries relating to a product "not at the center" of the challenged conduct. (*Id.* at 36.)

Third Circuit law requires plaintiffs to show they were targeted by a defendant's actions, *Steamfitters*, 171 F.3d at 926–27, or that the harm was an integral byproduct of those actions, *Allegheny*, 116 F. Supp. 2d at 614. Such a showing must leave the court with no doubt the complained-of harm was "precisely the type of loss the claimed violations . . . would be likely to cause." *McCready*, 457 U.S. at 479.

Here, the Court finds Plaintiffs' sufficiently allege that Defendants' conduct was intended to target competitors, including Plaintiffs, by actively delaying competition in the market for generic Zetia with the knowledge and anticipation their conduct would affect Vytorin-related products and cause Plaintiffs and other competitors to pay more for brand-name products. Defendants correctly note Plaintiffs rely almost entirely on a single email (ECF No. 35 ¶ 96), in which a Glenmark representative noted Vytorin would be impacted in claiming Defendants intended to harm Vytorin-related products (ECF No. 45 at 17–18). However, the Court disagrees

with their characterization of these harms as "collateral." (*Id.* at 17.) The Court reads the email as anticipating actual, imminent harm to Vytorin products *because* of Defendants' anticompetitive conduct. Because Zetia is an indispensable component of Vytorin, logic suggests a higher price in the component would result in a higher price of the end product. The Court finds Plaintiffs' allegations of a conscious effort and objective by Defendants to prevent generic Zetia competition, with the knowledge it would affect Vytorin, plausibly show Defendants intended to harm Plaintiffs and other would-be producers of generic Vytorin products.

3. State Antitrust, Consumer Protection, and Unjust Enrichment Law Claims

In Counts I–V of their Amended Complaint, Plaintiffs seek relief under up to 31 state antitrust, unjust enrichment, and consumer protection laws, including Puerto Rico, for Zetia as well as Vytorin-related products. (ECF No. 35 ¶¶ 189, 201, 213, 221, 236.) Defendants argue all state law claims should be dismissed because they are not "truly *pleaded* claims," given they are listed in a long string of bullets but not differentiated in any meaningful way, such as by setting out the required elements. (ECF No. 43 at 58 (quoting *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 255–56 (D. Conn. 2015)).) Additionally, Defendants argue that because, in their view, Plaintiffs lack standing for Vytorin-related claims, the Court must also dismiss all such claims under state law. (*Id.* at 57–58.) Plaintiffs generally refute Defendants' argument for citing only a handful of general, non-binding, and "cherry-picked" cases to support asking the Court to strike claims under multiple state's laws. (ECF No. 44 at 32–34.) In their reply, Defendants reiterate the state law claims are only loosely referenced and specifically point to Plaintiffs' failure to cite case law in support of their argument against a proximate cause requirement for state law claims. (ECF No. 45 at 18–19.)

The Court agrees Plaintiffs have not "truly *pleaded*" the state law claims; rather, the Amended Complaint makes oblique references to state statutes without even describing the elements of each. (ECF No. 46 at 58; *see* ECF No. 35 ¶¶ 189, 201, 213, 221, 236.) Under *Twombly*'s well-established pleading standard, "a plaintiff's obligation [is] to provide the 'grounds' of his 'entitle[ment] to relief'" which "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" 550 U.S. 544, 555 (2007). Here, Plaintiffs do no more than gesture at state statutes, and fail to include even a "formulaic recitation of the elements" of causes of action under state law. *Id.* The Court therefore need not reach the other arguments made regarding this issue by Defendants at this time.

Therefore, Defendants' motion to dismiss Plaintiffs' Zetia and Vytorin-related claims under state antitrust, consumer protection, and unjust enrichment law is **GRANTED**, and Defendants' motion to dismiss Vytorin-related claims under federal antitrust law is **DENIED**.

C. Monopolization in Violation of Federal Antitrust Law – Counts I and V

Plaintiffs allege Defendants took a series of actions in a purposeful effort to delay competition and ultimately monopolize the market for generic Zetia. (ECF No. 35 ¶¶ 187–88, 233.) Plaintiffs claim Merck failed to disclose certain key information to the USPTO, which Plaintiffs argue amounts to fraud in pursuit of its patents. (*Id.*) Plaintiffs also contend Merck initiated meritless litigation against Glenmark, which resulted in a settlement agreement that Plaintiffs argue is in fact a reverse payment agreement. (*Id.*) Finally, Plaintiffs allege Merck wrongfully listed patents in the Orange Book for Zetia. (*Id.*) Each of these theories of liability is tied to some aspect of a patent approval or prosecution process. (*Id.*)

A patent grant is the exclusive right to use the patented invention, effectively granting a limited monopoly. *See United States v. Line Material Co.*, *et al.*, 333 U.S. 287, 300 (1948)

("[T]he precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition."). Under Section 2 of the Sherman Act, a plaintiff must plead two elements to state a monopolization claim: (1) a showing that the defendant possesses monopoly power in the relevant market; and (2) "the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 75 (3d Cir. 2010). The second element in Section 2 cases can be predicated on one or more theories, including without limitation *Walker Process* fraud, sham litigation, wrongful Orange Book listing, a reverse payment settlement, and an overarching scheme. *See In re Lipitor Antitrust Litig.*, MDL No. 2332, Master Dkt. No. 3:12-cv-2389, 2013 WL 4780496, at *15 (D.N.J. Sept. 5, 2013) (reversed on other grounds). Because patent holders enjoy considerable antitrust immunity, a plaintiff usually must either show a defendant obtained a patent through actual, *Walker Process* fraud or initiated a sham lawsuit with the intent to interfere with a competitor's business. *See In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998).

1. *Walker Process* Fraud on the United States Patent and Trademark Office

In Counts I and V of the Amended Complaint, Plaintiffs allege Defendants "knowingly, willfully, and wrongfully" preserved their monopoly power by failing to disclose key information to the USPTO, including by wrongfully listing patents that were not in fact relevant in the Orange Book for Zetia. (ECF No. 35 ¶¶ 187, 233.) Plaintiffs allege this was done with the specific intent to deceive and defraud the USPTO. (*Id.*)

Defendants move to dismiss Plaintiffs' theory of monopolization and monopolistic scheme for several reasons. First, Defendants point to their disclosure of certain scientific information, including relevant international publications, in the prosecution history and argue the information "cannot be deemed to have been withheld." (ECF No. 43 at 42 (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1185 (Fed. Cir. 1995)).) Defendants, as patent holders, also argue they have no duty to explain prior art to the examiner. (*Id.* at 43.) Moreover, Defendants insist Plaintiffs fail to sufficiently allege a specific intent to deceive by not including supporting facts, such as the names of specific individuals involved with the filing or prosecution of relevant patents (*id.* at 44–46), or adequately alleging the requisite materiality of any allegedly withheld information (*id.* at 46–49). Likewise, Defendants argue Plaintiffs do not allege sufficient facts regarding inventors purportedly omitted from the relevant patents, such as their names, or assert the requisite intent and materiality of the issue. (*Id.* at 49–51). And because these *Walker Process* claims fail, according to Defendants, the argument that Merck listed patents in the Orange Book knowing they were invalid, unenforceable, or inapplicable to Zetia and/or Vytorin must also fail as it is similarly deficient. (*Id.* at 53–54.)

Plaintiffs reiterate their position that the *Walker Process* fraud claims were sufficiently pled. (ECF No. 44 at 36.) First, Plaintiffs dispute Defendants' read of their arguments as turning on whether Merck disclosed certain prior art to the USPTO during prosecution of the RE '721 patent; instead, Plaintiffs allege Merck had critical scientific knowledge grounded in its own internal studies about relevant compounds—information Plaintiffs claim is material to patentability—that it intentionally withheld. (*Id.*) According to Plaintiffs, Defendants' argument this information is ultimately immaterial is contradicted by Merck's efforts to seek reissue of the RE '721 patent, during which it cancelled the allegedly anticipated claims and disclosed

previously withheld information. (*Id.* at 37.) Plaintiffs argue it is irrelevant to the fraud claim whether Defendants had a duty to disclose because Plaintiffs plausibly allege fraud in intentionally withholding material information from the patent examiner. (*Id.*).

Plaintiffs also point to the allegations regarding the intentional withholding of material information; taken as true, Plaintiffs insist these specific allegations show intent. (*Id.* at 38.) Plaintiffs further respond, with regard to the fraud theory based on intentionally withholding information regarding inventors of the RE '721 patent, that the *Mylan* decision should not be held against them as doing so would be an improper application of collateral estoppel doctrine, and Defendants' failure to challenge the sufficiency of these allegations illustrates that the Complaint provided adequate notice of the basis for Plaintiffs' claim. (*Id.* at 39.) Finally, Plaintiffs request leave to amend any of the above monopolization allegations deemed insufficiently pled by the Court. (*Id.* at 40.)

In reply, Defendants argue Plaintiffs' fraud claims do not meet the Rule 8 pleading standard, despite the extensive discovery taken in the MDL. (ECF No. 45 at 19–20.) Defendants insist Plaintiffs fail to plead fraud with particularity as required, contending the allegations lack evidence of a specific intent to deceive, the materiality of the information withheld, or that Defendants withheld or otherwise misrepresented patent inventors, such as by alleging the names of individuals who allegedly withheld information, what those individuals knew (or should have known) and when, which specific studies or publications were not disclosed, and the identities of the purportedly unnamed inventors. (*Id.* at 20–23.) Ultimately, Defendants contend dismissal of these theories is warranted because "Plaintiff do not allege the 'extremely high level of misconduct' necessary to sustain a *Walker Process* claim." (*Id.* at 25 (quoting *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556, 1563 (Fed. Cir. 1989).)

"[E]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability." 37 C.F.R. § 1.5. In *Walker Process*, a pivotal patent infringement case, the Supreme Court held that an action brought to enforce a fraudulently obtained patent violated Section 2 of the Sherman Act so long as all other Section 2 elements are met. 389 U.S. at 174. Later courts expounded on so-called *Walker Process* fraud claims, explaining *Walker Process* fraud is based in common law fraud, requires a showing of actual fraud on the USPTO, and is governed by Federal Circuit law. *See Daiichi Sankyo, Inc. v. Apotex, Inc.*, Civ. A. No. 030937, 2009 WL 1437815, at *5 (D.N.J. May 19, 2009). The higher pleading threshold for both intent and materiality in *Walker Process* fraud claims requires:

> [I]ndependent and clear evidence of deceptive intent together with a clear showing of reliance, i.e., that the patent would not have been issued but for the misrepresentation or omission. Therefore, for an omission such as a failure to cite a piece of prior art to support a finding of *Walker Process* fraud, the withholding of the reference must show evidence of fraudulent intent. A mere failure to cite a reference to the PTO will not suffice.

Nobelpharma, 141 F.3d at 1070–71 (emphasis added). For example, a court in this District found no clear and convincing evidence of fraudulent intent where a patent applicant incorrectly typed the date of a foreign patent similar to their own in a document filed with the USPTO, making it appear as if only one day separated the two patent applications. *See Daiichi Pharmaceutical Co., Ltd. v. Apotex, Inc.*, 441 F. Supp. 2d 672, 691–92 (D.N.J. 2006) (reversed on other grounds).

Schering and Merck's failure to disclosure information in their possession during the prosecution of the '115 and RE '721 patents regarding metabolization studies of the compound named "SCH48461," which included ezetimibe (or Zetia), comes close to meeting the

heightened standard for pleading a *Walker Process* fraud claim, but ultimately misses the mark. While the Amended Complaint notes the studies were conducted by Schering scientists "including inventors named on the '115 patent family" (ECF No. 35 ¶ 66), it does not provide their names, explain their roles or degree of involvement in the studies or the patent application process, or show connections between any individuals involved with the prosecution of the patents that began in the 1990s. Such critical facts might sufficiently allege a *Walker Process* fraud claim if they suggest a person of import in Schering and/or Merck had material information in their possession and, with knowledge of its materiality, intentionally withheld it from the USPTO and thereby fraudulently obtained the patents. But absent these precise allegations, the existence of the SCH48461 metabolization studies does not meet the pleading requirements. *See Nobelpharma*, 141 F.3d at 1070 ("[A] misrepresentation or omission must evidence a *clear intent to deceive the examiner* and cause the [USPTO] to grant an invalid patent.").

Therefore, Defendants' motion to dismiss the *Walker Process* fraud theory claim is **GRANTED**, and the claim is dismissed without prejudice and with leave to amend consistent with the guidance in this Opinion.

2. Sham Litigation Theory

Plaintiffs allege the lawsuit by Schering and MSP Singapore, as patent assignee and exclusive licensee, respectively, against Glenmark (and other generic Zetia and Vytorin manufacturers) asserting infringement of the RE '721 patent was meritless. (ECF No. 35 ¶¶ 187, 233.) In that lawsuit, Glenmark allegedly raised counterclaims and defenses including fraudulent procurement of the RE '721 patent and failure to discuss key material information to the USPTO against Schering. (*Id.* ¶¶ 85–92.) One month after the litigation was settled, Schering allegedly made declarations to the USPTO stating its patent "claim[ed] more than [it] had the right to claim" and referring to relevant scientific publications omitted from the original patent

application, which Plaintiffs assert amount to an admission that the Glenmark suit had no merit. (*Id.* ¶¶ 99–102.)

Defendants contend Plaintiffs' theory of monopolization or attempt to monopolize based on allegedly sham litigation against Glenmark fails because: (1) the suit reasonably asserted patent infringement; (2) Defendants won the related suit, *Mylan*, which makes the Glenmark suit meritorious by definition; and (3) the overarching theory of monopolization is based in *Walker Process* fraud, requiring additional factual allegations which are markedly absent. (ECF No. 43 at 51–53.) Finally, Defendants argue the Court should dismiss the monopolistic scheme claims on the same grounds; specifically, Defendants contend dismissal is warranted because the challenged conduct is immune from antitrust liability under *Noerr-Pennington*. (*Id.* at 54–55.)

Plaintiffs respond that Third Circuit cases like *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017), caution against violating collateral estoppel doctrine by applying final judgments from cases in which the plaintiff in a pending matter was not a party, and argue the same rationale should apply here. (ECF No. 44 at 40–41.) In reply, Defendants reiterate their position that the favorable decision in the *Mylan* case, the other action brought to enforce the RE '721 patent, should guide the Court to find the Glenmark suit similarly meritorious. (ECF No. 45 at 25–26.) Arguing *In re Lipitor* is inapposite, Defendants contend *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132 (3d Cir. 2017), compels a dismissal because the Third Circuit enunciated a single standard for all Hatch-Waxman suits triggered by Paragraph IV certifications. (*Id.* at 26–27.)

Under the *Noerr-Pennington* doctrine, antitrust law protects the right to petition the government and immunizes parties that exercise this right from antitrust liability. *In re Wellbutrin*, 868 F.3d at 147–48; *see E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365

U.S. 127, 138–40 (1961). But actions that disingenuously invoke antitrust immunity as smokescreens in order to interfere with the business enterprise of a competitor, commonly referred to as sham actions, are excluded from *Noerr-Pennington* protection. *See In re Wellbutrin*, 868 F.3d at 147–48. Determining whether a lawsuit is a sham is a two-step process. *See Professional Real Estate Investors, Inc., et al., v. Columbia Pictures Industries, Inc., et al.* ("*PRE*"), 508 U.S. 49, 61 (1993). First, the court must find the suit is objectively baseless, meaning that no reasonable person could expect to be successful on the merits; next, the court examines the litigant's subjective motivations to determine if the litigant sought to conceal direct interference with a competitor's business by wielding a government process "as an anticompetitive weapon." *Id.*; *see also Takeda*, 358 F. Supp. 3d at 394.

Plaintiffs bringing a sham litigation claim bear the burden of showing the action lacked legal viability before a court will consider any arguments concerning its purported anti-competitive economic ends. *Id.* However, "district courts within this Circuit have routinely prohibited parties from invoking the protections of *Noerr-Pennington* at the dismissal stage of a case in the context of patent suits, at which time the factual record remains undeveloped and insufficient for the purpose of determining whether a 'sham litigation' has been filed." *Takeda*, 358 F. Supp. 3d at 394 (quoting *FTC v. Shire ViroPharma, Inc.*, No. 17-131, 2018 WL 1401329, at *7 (D. Del. Mar. 20, 2018) ("[W]hether [the patent holder's] activity was in fact a sham under either standard is a factual inquiry, which cannot be resolved at the motion to dismiss stage.")); *see also In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, Civ. A. No. 06-52, 2010 WL 1485328, at *10 (D. Del. Apr. 13, 2010) ("The court, however, cannot [determine whether *Noerr-Pennington* applies] at the motion to dismiss stage, because it is fact intensive.").

The Court reads Plaintiffs' sham litigation theory as predicated on its *Walker Process* fraud argument, as Plaintiffs make the declarations and corrections Defendants made in applying for reissue of the RE '721 patent a focal point of their allegations. In light of the Court's determination that Plaintiffs failed to meet the heightened standard for pleading actual fraud, *supra* Section III.C.1., it stands to reason its sham litigation theory cannot go forward premised on the same core allegations that Defendants knowingly and intentionally misrepresented material information to fraudulently obtain the patents in question. However, the case law suggests this issue may be more appropriate for summary judgement given it involves a fact-intensive inquiry, which, in this case, would include a deeper dive into critical missing information regarding possible communications between and among Defendants.

Therefore, Defendants' motion to dismiss the sham litigation theory claim is **GRANTED**, and the claim is dismissed without prejudice and with leave to amend in accordance with guidance in this Opinion.

3. Wrongfully Listing Patents in the Orange Book

On top of the *Walker Process* fraud and sham litigation theories of monopolization, Plaintiffs allege Defendants wrongfully listed patents in the Orange Book for Zetia they either knew did not cover Zetia or were invalid. (ECF No. 35 ¶¶ 71–73.) Plaintiffs allege Defendants were thereby able to assert claims of patent infringement against competitors and reduce competition in the market for Zetia and related products. (*Id.* ¶¶ 73–74, 187, 233.) Defendants contend the Court should dismiss this Orange Book theory for the same deficiencies as the *Walker Process* and sham litigation theories. (ECF No. 43 at 53–54.) Plaintiffs restate their *Walker Process* fraud and sham litigation claims regarding the RE '721 patent, insisting they were sufficiently pled. (ECF No. 44 at 42.) Defendant responds simply the Court must dismiss

because Plaintiffs have not met their burden of showing any patent was obtained through fraud on any basis, including by wrongfully listing patents. (ECF No. 45 at 27.)

An Orange Book listing can only be deemed wrongful if the relevant patent was obtained through actual fraud or objectively had no merit. *See Daiichi Sankyo*, 2009 WL 1437815 at *9. Without a finding of fraud, an Orange Book listing claim cannot proceed. *See id.* Accordingly, Defendants' motion to dismiss the Orange Book theory claim is **GRANTED**, and the claim is dismissed without prejudice and with leave to amend in accordance with the guidance in this Opinion.

D. Overarching Monopolistic Scheme – Count V

Plaintiffs argue Defendants "knowingly, willfully, and wrongfully" engaged in a scheme to monopolize with Schering by: (1) withholding material information regarding patents and inventors during the prosecution of the '115 and RE '721 patents; (2) listing or causing to be listed invalid patents in the Orange Book that did not cover Zetia and/or Vytorin; (3) initiating baseless, sham litigation against generic Zetia and Vytorin manufacturers like Glenmark and others; and (4) entering into the Zetia Settlement Agreement which allegedly included an illegal reverse payment to delay generic entry and extend Merck's monopoly. (ECF No. 35 ¶¶ 231–33.)

Defendants contend the monopolistic scheme claim should be dismissed because Plaintiffs are unable to show Defendants should not be afforded *Noerr-Pennington* immunity given the allegedly deficient *Walker Process* fraud and sham litigation claims, *supra* Section III.C.1–2. (ECF No. 43 at 54.) In opposing the Motion, Plaintiffs reiterate that the string of alleged conduct, taken together, suggests a monopolistic scheme; moreover, in Plaintiffs' view, Defendants "merely cross-reference their earlier arguments" regarding the *Walker Process* fraud and sham litigation claims. (ECF No. 44 at 42–43.) In regard to the Orange Book theory of

monopolization, Defendants reply the Court must dismiss because Plaintiffs have not met their burden of showing any patent was obtained through fraud on any basis. (ECF No. 45 at 27.)

When specific allegations of conduct are determined to be insufficient to support a claim for relief, a separate claim that is nothing more than a combination of those specific allegations must also be deemed meritless. *In re Lipitor*, 2013 WL 4780496 at *23 (reversed on other grounds). Accordingly, Defendants' motion to dismiss Plaintiffs' overarching monopolization scheme claim is **GRANTED**, and Count V is dismissed without prejudice and with leave to amend in accordance with guidance in this Opinion.

E. Conspiracy to Monopolize – Count II

In Count II, Plaintiffs allege Defendants conspired to monopolize the market for generic Zetia products by engaging in an anticompetitive scheme comprised of a series of purportedly intentional and wrongful actions that sprung out of Merck's lawsuit against Glenmark and the subsequent settlement agreement, which Plaintiffs allege is as a reverse payment agreement. (ECF No. 35 ¶¶ 198–200.) Defendants argue the conspiracy to monopolize claims based on an alleged conspiracy between Merck and Schering should be dismissed because Plaintiffs' arguments in this regard are conclusory and lack facts "plausibly suggesting a unity of purpose, a common design and understanding, or a meeting of the minds." (ECF No. 43 at 56 (quoting *Howard Hess Dental Lab'ys Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 255–57 (3d Cir. 2010)).) Defendants also contend Plaintiffs fail to show any specific intent of achieving an illegal monopoly. (*Id.* at 56–57.) In *Howard Hess*, the Third Circuit affirmed a dismissal of a conspiracy to monopolize claim because plaintiffs relied on conclusory allegations. 602 F.3d at 256 ("Plaintiffs' allegations do not offer even a gossamer inference of any degree of coordination . . . . "). Defendants likewise argue for dismissal of Plaintiffs' claim because their

factual allegations showing unilateral conduct and otherwise lawful business endeavors—such as Schering's prosecution of the RE '721 patent and the Merck-Schering joint venture, respectively—do not support their conclusory allegations of conspiracy. (*Id.* at 56.)

In their Opposition, Plaintiffs contend the Merck and Schering conspiracy claim is like those made in the seminal *Suboxone* case. (ECF No. 44 at 45.) As in *Suboxone*, 2017 WL 4910673, at *12–13, where the court determined plaintiffs plausibly alleged a conspiracy to monopolize based on facts showing two companies were both involved in developing and marketing an opioid addiction drug, Plaintiffs contend they pled sufficient facts showing Defendants coordinated in the development of generic versions of Zetia and in filing for patents before the FDA "in furtherance of their monopolistic goals[,]" which raise an inference of an illegal conspiracy to monopolize. (*Id.*)

In reply, Defendants argue Schering and Merck, through its subsidiary MSP Singapore Co. LLC, had a patentee/licensee relationship, and therefore a unified interest, in pursuing the Glenmark litigation. (ECF No. 45 at 27–28.) As such, this "complete unity of interest" defeats any conspiracy claim. (*Id.*); *Duke Univ., Allergan, Inc. v. Akorn, Inc.*, No. 3:18-cv-14035, 2019 WL 4410284, at *11 (D.N.J. Sept. 16, 2019). Additionally, Defendants note the dearth of specific factual allegations bearing on any agreement or conspiracy, lawful or otherwise, between Merck and Schering, and contend Plaintiffs' allegations of communications between the two parties do not give rise to an inference of an agreement without more. (*Id.* at 28 n.12.) Ultimately, Defendants contend Plaintiffs fail to show specific intent to conspire. (*Id.* at 28–29.)

"[D]istrict courts have held that [] parties with unified interests, such as a patent holder and licensee, are incapable of conspiring [with one another for purposes of antitrust law]." *Duke Univ.*, 2019 WL 4410284 at *11. This rule emerges from the general principle, stemming from

joinder rules in federal civil procedure, that a patent holder or assignee should be joined in any patent infringement litigation "brought by an exclusive licensee having fewer than all substantial patent rights." *Id.*

Given it is undisputed Schering and Merck have a patentee-licensee relationship, the law regards them as having had a single, indivisible interest in the enforcement action against Glenmark. *Id.* Plaintiffs therefore cannot plead a conspiracy between them. Accordingly, Defendants' motion to dismiss the conspiracy to monopolize claim (Counts II) is **GRANTED**.

IV. CONCLUSION

For the reasons set forth above, and for good cause having been shown, Defendants' Partial Motion to Dismiss (ECF No. 43) is **GRANTED** in part and **DENIED** in part. Specifically, the Court grants dismissal of Plaintiffs': (1) *Per Se* Monopoly theory from Count III; (2) *Walker Process* fraud, sham litigation, and Orange Book Monopolization theories from Counts I and V; (3) Monopolistic Scheme claims (Count V in its entirety); (4) Conspiracy to Monopolize theory from Count II; and (5) all state law claims asserted in Counts I–VI. Apart from the *per se* monopoly theory in Count III and the conspiracy to monopolize claim (Count II), which are dismissed with prejudice, all remaining dismissals are granted without prejudice and with leave to amend. Defendants' motion to dismiss Plaintiffs' claims for Vytorin damages is denied. An appropriate order follows.

Date: December 30, 2024

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE